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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,851	11/14/2005	Kunihiko Matsushita	KPO-TSC-P2/TK-91/US	2134
44702 7590 09/24/2010 OSTRAGER CHONG FLAHERTY & BROITMAN PC 570 LEXINGTON AVENUE FLOOR 17 NEW YORK, NY 10022-6894				
EXAMINER				
MERCIER, MELISSA S				
ART UNIT		PAPER NUMBER		
1615				
NOTIFICATION DATE		DELIVERY MODE		
09/24/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Office Action Summary

**Application No.**

10/556,851

**Applicant(s)**

MATSUSHITA ET AL.

**Examiner**

MELISSA S. MERCIER

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 7-2-10.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/CD)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Summary***

Receipt of Applicants Remarks and Amended Claims filed on July 2, 2010 is acknowledged. Claims 1-13 are pending in this application.

***Withdrawn Objections/Rejections***

***Claim Objections***

The objection to claim 5 because it was identified as "currently amended" however; the Examiner was unable to determine what has been amended in the claim has been withdrawn in view of Applicants amendment to the claim and Applicants acknowledgement that the previous identifier was a typographical error.

***Claim Rejections - 35 USC § 103***

The rejection of claims 1-3, 5-7, and 9-11 under 35 U.S.C. 103(a) as being unpatentable over Hirano et al. (JP 11-001441) in view of Grawe et al. (US Patent 6,902,741) in view of Applicants amendment to claim 1 to exclude an alcohol.

Claims 4, 8, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirano et al. (JP 11-001441) in view of Grawe et al. (US Patent 6,902,741) and further in view of Azuma et al. (US Patent 5,200,190) has been withdrawn in view of Applicants amendment to claim 1 to exclude an alcohol.

***Newly Applied Rejections/Objections***

***Claim Objections***

Claims 5-8 objected to under 37 CFR 1.75 as being a substantial duplicate of claims 1-4. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has amended the independent claims to exclude alcohol; however, the Examiner was unable to locate support for such exclusion. While it is acknowledged that the working example does not have alcohol, this does not provide adequate written basis for its exclusion. **This is a new matter rejection.**

Applicant is advised that once the new matter is removed from the claims, the rejections indicated as withdrawn above will be reapplied.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maki et al. (US 2004/0039356) in view of Hirano et al. (JP 11-001441).

Maki discloses a composition for external preparation (i.e. adhesive preparations). used for hormone replacement therapy (abstract).

Estrogen including 17  $\beta$ -estradiol (paragraph 0028) and Progesterone, including norethisterone acetate is disclosed (paragraph 0029) which can be present in the amount of 0.5-10% by mass (paragraph 0028) and 1.0-10% by mass (paragraph 0029), respectively.

The adhesive comprise:

\*polyvinylpyrrolidone in the amount of 1-10% by mass (paragraph 0011).

\*vegetable oils, which are softeners, in the amount of 1-25% by mass (paragraph 0008).

\*rubber polymers, including styrene-isoprene-styrene block copolymers are disclosed (paragraph 0024).

\*hydrogenated rosin glycerin ester resins can be included (paragraph 0034);

Example 1 discloses it is present in the amount of 5.0% by mass.

The adhesive composition is applied to a polyethylene terephthalate film can be laminated with paper or cloth. (paragraph 0038).

Maki does not disclose the amount of the SIS copolymer to be used.

The thickness of the layers were also not disclosed, however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have prepared a film in varying thicknesses based on the needs of the patch. Applicants attention is directed to MPEP 2144.04 IV, which discloses changes in size and shape are not patentably distinct over a device which would perform the same function, in this cases Maki is also drawn to external patches for percutaneous delivery of estradiol.

Hiraro discloses a percutaneous absorption patch comprising:

- a. 10-30% of a styrene-isoprene-styrene block copolymer;
- b. 10-60% of a softening agent;
- c. 20-60% of a tackifying resin;

The medicinal ingredient is an estrogen, such as estradiol or progesterone such as norethisterone at a level of 0.1-10% weight (abstract). Rosin esters are disclosed for use as the tackifiers (paragraph 0016). The patch is a laminated film (paragraph 0017).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the amount of the SIS copolymer disclosed by Hiraro into the adhesive disclosed by Maki since both references are drawn to drug in adhesive compositions comprising SIS, softening agents, and tackifying resins. While it is acknowledged that Hiraro requires the use of hexylene glycol as discussed by

Applicant, the Examiner respectfully points Applicant to the teachings of Maki which do not require hexylene glycol, yet still functions as recited.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MELISSA S. MERCIER** whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/  
Examiner, Art Unit 1615

/Carlos A. Azpuru/  
Primary Examiner, Art Unit 1617